U.S. Department of Justice

United States Attorney
Southern District of New York

The Silvio J. Mollo Building
One Saint Andrew's Plaza
New York, New York 10007

August 8, 2024

VIA ECF
The Honorable Arun Subramanian
United States District Court
Daniel Patrick Moynihan Courthouse
500 Pearl Street
New York, New York 10007

Re: United States v. US Compounding, Inc., 24 Cr. 423 (AS)

Dear Judge Subramanian:

The Government respectfully writes in connection with the sentencing of US Compounding, Inc. ("USC"), which is currently scheduled for August 15, 2024 at 3 p.m. USC, through its employees and executives, perpetrated a years-long fraud that ran contrary to the foundational regulatory regime governing USC's operations. The Food Drug and Cosmetic Act ("FDCA"), among other things, erected meaningful checks on the flow of drugs within the United States. One of the key restrictions set forth in the FDCA is the requirement that drugs requiring a prescription actually be distributed pursuant to a legitimate prescription. This basic prerequisite is enshrined in state law and rooted in common sense. USC, which operated a compounding pharmacy registered with the FDA, knew full well the panoply of regulations that restricted their dissemination of prescription drugs, including those intended for animals. Notwithstanding that cardinal principle, and notwithstanding the pushback of dissident employees, senior leadership and other USC personnel orchestrated an elaborate scheme to distribute veterinary drugs under bogus prescriptions.

The Government has carefully considered its view of USC's culpability in this matter and has reached a resolution with USC and its parent company, DMK Pharmaceuticals Corp. ("DMK"), that appropriately reflects the severity of the crime while still providing partial credit for the company's cooperation. The Government is likewise mindful that because DMK (and, by extension, USC) is in bankruptcy proceedings, any claim filed in bankruptcy court seeking recovery of fine or forfeiture amounts will likely lead to only partial recovery of whatever monetary penalties this Court imposes at sentencing. For the foregoing reasons, having weighed all these factors, the Government respectfully requests that the Court impose a criminal fine in the amount of $16,959,112 and enter a forfeiture money judgment in the amount of $4,239,778.

I. Background

As set forth in the Statement of Facts,[1] beginning in approximately 2015, while USC—a drug compounding company based in Arkansas that supplied prescription medications and compounded drugs—was still a privately-held corporation, a USC sales representative ("Sales Rep 1") entered into an illegal arrangement with a complicit veterinarian (the "Veterinarian"). Pursuant to that arrangement, Sales Rep 1 would use the Veterinarian's state veterinary licenses to generate records of false prescriptions for a particular equine drug (the "Drug"), in order to justify shipping it directly to consumers, including to consumers in the Southern District of New York, who otherwise lacked a valid prescription. The Veterinarian was promised a ten percent commission of all patient-specific sales generated using his credentials, even though Sales Rep 1, an executive at USC (the "USC Executive"), and Sales Rep 1's sales team knew that the Veterinarian did not have a valid Veterinarian-Client-Patient Relationship ("VCPR") with the clients receiving the medications USC shipped. Sales Rep 1 and his sales team generated approximately $1 million in sales annually as a result of the false prescription scheme, which comprised approximately one-third of Sales Rep 1's total sales of USC drugs.

On March 28, 2016, Adamis Pharmaceuticals Corporation ("Adamis") announced that it had acquired USC, with USC surviving as a wholly-owned subsidiary of Adamis. Although Adamis was a publicly-traded company based in California, USC continued to operate in its headquarters in Arkansas, and much of its staff remained employed, including Sales Rep 1 and the USC Executive. Following the acquisition, an executive of Adamis (the "Adamis Executive") was made aware of the Scheme and the Veterinarian's role in it. The Adamis Executive wanted to grow the Scheme in order to increase USC's and, by extension, Adamis' revenue. In or about October 2016, the Adamis Executive, Sales Rep 1, and the USC Executive discussed entering into a sham "consulting agreement" with the Veterinarian, which purported to employ the Veterinarian as a consultant of USC's for the development of new equine medications. The purpose of the sham agreement was not, however, for consulting services, but to conceal the kickbacks the Veterinarian was being paid as part of the Scheme, by making those payments appear to reflect an hourly fee for consultations.

The Adamis Executive, Sales Rep 1, and the USC Executive intended to continue the Scheme and the provision of commission payments to the Veterinarian. Although a consulting agreement was prepared, it was never fully executed. Nonetheless, the Adamis Executive, Sales Rep 1, and the USC Executive intended to put forth the Veterinarian as a consultant if the commission payments were ever questioned. At various points following Adamis' acquisition of USC, the USC Executive, the Adamis Executive, and others discussed expanding the scheme to include other veterinarians in order to illegally enhance USC's revenue. Over the course of the Scheme, USC generated over $4.2 million in revenue as a result of the illegal sales of the Drug.

In approximately December 2019, the head of the USC pharmacy responsible for fulfilling orders of the Drug ("Pharmacist-1") resigned due to USC's failure to halt the practice of fulfilling orders of the Drug based on unverified prescriptions. Pharmacist-1's replacement ("Pharmacist-2") refused to fulfill any further orders for prescription drugs predicated on

[1] The Statement of Facts was appended as Attachment A to the parties' plea agreement.

unverified prescriptions submitted by USC's sales representatives. Pharmacist-2 raised concerns regarding USC's prescription practices with the Adamis Executive, the USC Executive, and Sales Rep 1, including Pharmacist-2's concern that the submitted prescriptions did not involve a VCPR and were sometimes submitted by USC sales representatives. ,

Pharmacist-2's complaints were largely dismissed. In an effort to ameliorate the submission of fraudulent prescriptions, Pharmacist-2 successfully convinced Adamis to implement a new veterinary software platform that was intended to eliminate the involvement of USC's sales representatives in the creation or submission of prescriptions in connection with orders. However, the Adamis Executive, the USC Executive, and Sales Rep 1 insisted that sales representatives be permitted to continue submitting prescriptions through the new software, and ultimately prevailed. Consequently, in or about September 2020, Pharmacist-2 and two other pharmacists employed at USC resigned. A fourth pharmacist employed at USC resigned the following week. Following the pharmacist resignations, sales representatives were permitted to enter prescriptions on behalf of the prescriber and/or the consumer on the new software platform employed by USC. USC sales representatives continued to submit false prescriptions in conjunction with orders of the Drug. Sales Rep 1 directed the Veterinarian to indicate through the software that the prescriptions issued using his credentials were valid, even though they were not.

In or about July 2020, in response to increased perceived scrutiny of USC's operations, USC sales representatives ceased submitting prescriptions for the Drug in the name of the Veterinarian. Although USC sales representatives continued to sell the Drug to individuals, they did not record those transactions as direct-to-consumer sales within USC's internal recordkeeping system. Instead, USC sales representatives falsely classified direct-to-consumer sales of the Drug as sales of office stock to the Veterinarian. Under guidance issued by the FDA, a Veterinarian may buy compounded drugs in bulk without prescriptions so long as the Veterinarian ultimately issues a valid prescription when those drugs are distributed to a consumer or directly dispensed to the receiving animal. USC sales representatives exploited the FDA guidance by concealing illegal sales to consumers through office stock sales to the Veterinarian, thereby avoiding the need to generate false prescriptions. According to USC's internal sales data, sales of the Drug to the Veterinarian's practice increased proportionally as direct-to-consumer sales of the Drug declined.

In or about April 2021, the Arkansas State Board of Pharmacy issued an Order and Notice of Hearing directed to the pharmacist who replaced Pharmacist-2. Prior to any hearing, USC settled the allegations and entered into a consent order wherein USC agreed to cease all operations in Arkansas, and USC agreed to relinquish its Arkansas State licenses as a pharmacy and wholesale distributor. USC also entered into a resolution in which they made the following factual admissions: i) USC "failed to ensure prescribing veterinarians were licensed in the state into which product was ordered and/or shipped"; ii) USC "allowed for issuance of veterinary legend products directly to consumers without receipt of a legal prescription"; iii) USC "provided remuneration directly to a veterinarian in connection with a veterinary prescription"; iv) USC "provided veterinary prescriptions drugs to animal owners without the authorization of a licensed veterinarian and a prescription"; and v) USC "filled veterinary prescriptions for patients that did not have a valid practitioner-patient relationship."

USC was historically subject to a number of state disciplinary actions as a result of its failure to comply with state laws governing the distribution of the drugs USC compounded.

- In 2008, the Colorado Board of Pharmacy disciplined USC for not complying with data submission requirements required by Colorado's prescription drug monitoring program, despite having received several non-compliance letters from the Board of Pharmacy. In 2010, the Hawaii Board of Pharmacy instituted a reciprocal disciplinary action for USC's failure to report the Colorado disciplinary action.

- In 2014, the Colorado Board of Pharmacy disciplined USC for distributing a drug into Colorado pursuant to a prescription that was not patient-specific, which violated Colorado rules regarding non-resident pharmacies. Subsequently: i) the Michigan Board of Pharmacy disciplined USC on the basis that its license had been subject to a civil or administrative penalty (*i.e.*, the 2014 Colorado action); and ii) the Virginia Board of Pharmacy instituted a disciplinary action on the basis of USC's failure to disclose the same 2014 Colorado action.

- In 2015, the South Carolina Board of Pharmacy disciplined USC in connection with the recall of certain products that USC had distributed in South Carolina and issued a temporary suspension of USC's license in connection with USC's inability to substantiate the sterility of certain products.

- Also in 2015, the Minnesota Board of Pharmacy disciplined USC for compounding and distributing prescription drugs for office use between April 2013 to September 2014.

- In 2017, USC received a citation from the California Board of Pharmacy for conducting business in the state without a license. After USC was acquired by Adamis, the California Board of Pharmacy denied the application for a change of ownership from USC to Adamis, then penalized USC for continuing to operate in California without approval from the Board of Pharmacy.

- In 2017, the Texas Board of Pharmacy instituted disciplinary proceedings against USC on two grounds: first, for USC's failure to disclose the 2008 disciplinary action instituted by the Colorado Board of Pharmacy in a prior application for renewal of USC's Texas State license; and second, for operating under the supervision of a pharmacist who was not licensed in Texas, as required under Texas State law, between September 2016 and March 2017. USC did not admit any wrongdoing in connection with the resolution of the second allegation.

- In 2018, the Kansas Board of Pharmacy instituted disciplinary proceedings in connection with deficiencies related to USC's facilities as reported by the FDA following inspections on August 1, 2005, July 15, 2016, and February 7, 2019, and in connection with prior disciplinary actions that had been taken against

USC by other Boards of Pharmacy. The proceedings were dismissed in 2021 when USC announced it was ceasing operations.

- Also in 2018, the Michigan Board of Pharmacy instituted disciplinary proceedings in connection with deficiencies related to the pharmacist-in-charge's oversight of USC's procedures.

- In 2019, the Maryland Board of Pharmacy instituted disciplinary proceedings against USC for having dispensed drugs wholesale without a wholesale drug distributor permit and without valid prescriptions, and for distributing drugs into the State of Maryland during periods of time when USC's pharmacy license had lapsed.

II. Guidelines Calculation

As the Court is aware, on July 9, 2024, USC pled guilty to a two-count Information charging USC with mail fraud conspiracy and conspiracy to commit drug adulteration and misbranding. As part of the Plea Agreement, the parties waived preparation of a Presentence Investigation Report. As set forth in the Plea Agreement, the parties agree that a faithful application of the U.S.S.G. to determine the applicable fine range yields a base offense level of 7 and total offense level of 27 based on U.S.S.G. §§ 2B1.1(a) and (b)(1)(J), because Counts One and Two are grouped into a single group pursuant to the factors in U.S.S.G. § 3D1.2 and 3D1.3(a). The sentence of a fine is calculated as follows:

a. Base Fine. Based upon U.S.S.G. § 8C2.4(a)(1), the base fine is that associated with the offense level fine enumerated under U.S.S.G. § 8C2.4(d), which, at offense level 27, is $8,500,000

b. Culpability Score. Based upon U.S.S.G. § 8C2.5, the culpability score is 6, calculated as follows:

(a)	Base Culpability Score	5
(b)(4)	Had 50 or more employees and an individual within substantial authority participated in, condoned, or was willfully ignorant of the offense	+ 2
(g)(2)	Cooperation, Acceptance	- 1
	TOTAL	6

Calculation of Fine Range:

Base Fine	$8,500,000

Multipliers	1.2 (min)/2.4 (max)
Fine Range	\$10,200,000 (min)/ \$20,400,000 (max)

Given that the statutory maximum fine is limited to twice the gross pecuniary gain or twice the gross pecuniary loss resulting from the offense, whichever is greatest, the statutory maximum fine that may be applied for Counts One and Two combined is \$16,959,112 (Title 18, United States Code, Section 1349 and Title 18, United States Code, Sections 3571(c) and (d)).

III. Procedural History

The Government subpoenaed USC in or about May 2021 and USC's parent company promptly retained outside counsel and launched an internal investigation into the misconduct that is now alleged in the Statement of Facts. In the course of its investigation, USC, through its parent company, made multiple presentations to the Government regarding its findings and ultimately entered into plea negotiations with the Government. In February 2024, while those negotiations were still ongoing, USC's parent company, and some of its direct and indirect subsidiaries including USC, filed for Chapter 11 bankruptcy relief in the U.S. Bankruptcy Court for the District of Delaware styled as *In re DMK Pharmaceuticals Corp., et al.*, Case No. 24-10153 (the "Bankruptcy Proceedings"). USC's parent company is consequently in the process of liquidating its assets, including any remaining assets of the Defendant.

After filing for bankruptcy, USC's Board of Directors authorized a representative to enter into the Plea Agreement with the Government. In the Plea Agreement, USC agreed with the Government that based on the application of the U.S.S.G., the appropriate total criminal fine would be no less than \$10,200,000 and no more than the statutory maximum allowable fine of \$16,959,112. As to the forfeiture amount, "[t]he Defendant . . . admits the forfeiture allegation with respect to Counts One and Two of the Information, and consents to the entry of a forfeiture money judgment in the amount of \$4,239,778 in United States currency (the "Money Judgment") representing (i) the proceeds traceable to the offense charged in Count One of the Information that it personally obtained, and (ii) the value of adulterated and misbranded drugs that the Defendant introduced into interstate commerce and sold, dissipated, or otherwise rendered unavailable associated with Count Two of the Information." The Plea Agreement also specifies that "if the Court rejects this Agreement, the Court must: (a) inform the parties that the Court rejects the Agreement; (b) advise the Defendant's counsel that the Court is not required to follow the Agreement and afford the Defendant the opportunity to withdraw its plea; and (c) advise the Defendant that if the plea is not withdrawn, the Court may dispose of the case less favorably toward the Defendant than the Agreement contemplated."

IV. The Maximum-Allowable Fine Is Sufficient But Not Greater Than Necessary

The Government respectfully submits that a particularized consideration of the factors set forth in 18 U.S.C. § 3553(a) demonstrates that a fine of \$16,959,112 and forfeiture of \$4,239,778 is sufficient but not greater than necessary to comply with the purposes of sentencing for the defendant. The proposed criminal fine, which contemplates the maximum authorized financial

penalty, is appropriate given the nature and circumstances of the offense, the history and characteristics of USC, particularly in light of its parent company's liquidation, and the need for just punishment and general deterrence. See 18 U.S.C. §§ 3553(a)(1) & (a)(2).

The nature and circumstances of the offense and the history and characteristics of USC counsel in favor of a significant criminal fine. USC turned its pharmacy into a factory that churned out a particular equine drug with illegitimate prescriptions in order to promote USC's bottom line and, in turn, the financials of USC's parent company. USC was regulated by the FDA and various state boards of pharmacy and had obligations to its regulators and customers to ensure compliance with the law. USC grossly abdicated that responsibility. Notably, USC's practice, initiated when USC was still a private company, continued even after USC was acquired by Adamis, a publicly-traded corporation that had even more extensive obligations to regulators, investors, analysts, and others to truthfully represent USC's financial condition and its compliance with all applicable laws. USC employees engaged in the criminal conduct for years. Even when internal whistleblowers attempted to clean up USC's practices, USC employees nonetheless persisted in their crimes by, for example, bypassing new software that Pharmacist-2 insisted be implemented and adapting the scheme to ensure that it could continue.

USC engaged in criminal activity for years, and the scheme was both sophisticated and extensive. It required the complicity of multiple employees and involved senior executives. And the scheme was conducted against the backdrop of USC having sustained multiple violations by multiple state boards of pharmacy, all while failing to reform its corrupt practices. Further, the violations of law that USC engaged in were not esoteric or murky legal technicalities: they fell in the heartland of USC's operations. There is no question that USC's employees and executives appreciated that what they were doing was wrong, yet they nonetheless continued the criminal conduct even when faced with internal pushback. USC finally ceased the criminal scheme only after the Government subpoenaed USC and made its investigation overt.

In calculating the applicable Guidelines range, the Government has already afforded USC a one-point reduction of the offense level on the basis of the key factors considered by the Government when evaluating corporate resolutions, including the remedial measures USC undertook to improve their internal controls and USC's cooperation in the Government's investigation. Consequently, the offense level calculation and ensuing Guidelines range for a criminal fine already take into account USC's cooperation in the Government's investigation. No further reduction is warranted.

Significantly, imposing the statutory maximum fine is warranted here given that USC is in bankruptcy proceedings. As a result of the bankruptcy, the Government will be required to submit a claim to recover a fine or forfeiture amount, and the Government is unlikely to recover the full amount to which it is entitled. Mindful of these constraints, the Government respectfully submits that the maximum-allowable criminal fine will boost the overall dollar amount that the Government can expect to recover from USC as a result of the company's guilty plea, and will effectively communicate the severity of USC's conduct, fulfilling the purposes of just punishment and general deterrence. These limitations on the Government's recovery distinguish this case from the corporate resolutions cited in the defendant's sentencing submission. *See* USC Sentencing Subm. at 6-7. While other companies may have been ordered to pay comparable or greater amounts

than the high-end of the Guidelines Range, in those cases, the Government was entitled to recover from the corporation the entirety of any monetary penalty imposed by the district court. Not so here. The Government's ability to recover from USC even a substantial portion of whatever criminal fine is imposed is uncertain at best.

Finally, the need for deterrence is particularly important in a case like this one given that the discretion afforded to pharmacies, like USC, and medical professionals, like veterinarians, makes the crime prosecuted here difficult to detect, investigate, and prosecute. *See, e.g.*, *United States* v. *Heffernan*, 43 F.3d 1144, 1149 (7th Cir. 1994) ("Considerations of (general) deterrence argue for punishing more heavily those offenses that either are lucrative or are difficult to detect and punish, since both attributes go to increase the expected benefits of a crime and hence the punishment required to deter it."); *United States* v. *Martin*, 455 F.3d 1227, 1240 (11th Cir. 2006) ("Because economic and fraud-based crimes are 'more rational, cool, and calculated than sudden crimes of passion or opportunity,' these crimes are 'prime candidate[s] for general deterrence.' (quoting Stephanos Bibas, *White-Collar Plea Bargaining and Sentencing After Booker*, 47 Wm. & Mary L. Rev. 721, 724 (2005)) (alteration in original)). All of this militates in favor of imposing the maximum fine allowed by law.

Conclusion

The Government respectfully submits that the proposed criminal fine of $16,959,112 would be sufficient, but not greater than necessary, to serve the legitimate purposes of sentencing set forth in Title 18, United States Code, Section 3553(a).

Respectfully submitted,

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by: /s/ .
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cc: Rizwan Qureshi, Esq. (via ECF)